



GUIDANCE DOCUMENT FOR REPORT OF THEFT, LOSS, OR RELEASE OF SELECT AGENTS AND TOXINS

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 01/31/2006



INTRODUCTION

The "Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (Public Law 107-188; June 12, 2002) requires that the United States improve its ability to prevent, prepare for, and respond to bioterrorism and other public health emergencies. It necessitates that individuals possessing, using or transferring agents or toxins deemed a severe threat to public, animal or plant health, or to animal or plant products, notify either the Secretary of the Department of Health and Human Services (HHS) or the Secretary of the Department of Agriculture (USDA). Subsequent to enactment of this law, requirements for possession, use, and transfer of select agents and toxins were published by HHS (42 CFR 73) and by USDA (7 CFR 331 and 9 CFR 121).

Responsibility for providing guidance on this form was designated to the Centers for Disease Control and Prevention (CDC) by the Secretary, HHS, and to the Animal and Plant Health Inspection Service (APHIS) by the Secretary, USDA. In order to minimize the reporting burden to the public, APHIS and CDC have developed a common reporting form for this data collection. This form (APHIS/CDC Form 3) is designed to assist entities in complying with this legal obligation.

An entity is required by regulation (7 CFR 331.19, 9 CFR 121.19, and 42 CFR 73.19) to contact APHIS (telephone: 301-734-5960, facsimile: 301-734-3652) or CDC (telephone (404-498-2255), facsimile (404-498-2265), or e-mail (lrsat@cdc.gov)) immediately upon discovery of a theft, loss, or a release (occupational exposure or release of an agent or toxin outside of the primary barriers of the biocontainment area) of a select agent and toxin not authorized under a federal act. After the initial reporting, this form should be sent directly to APHIS or CDC, as appropriate, within 7 calendar days after the discovery of theft, loss, or release of select agents or toxins. This requirement is not satisfied by reporting the theft or significant loss in any other manner. A copy of the completed form and attachments must be kept by the entity for three years.

Notification of the proper agencies is important to assure that emergency response efforts, including medical intervention and follow-up surveillance of human or other animals potentially exposed by release of the select agents and toxins(s), are accomplished in a timely matter, if appropriate. For release of HHS select agents or toxins, the RO should also notify the local and State Health Department. For USDA agents, the State Veterinarian should be contacted; for restricted plant pathogens, the State Plant Regulatory Official should be notified. For HHS/USDA overlap agents both the State Veterinarian and State Health Departments should be notified. In the case of theft or loss, the local police and Department of Justice should be notified, as appropriate.

INSTRUCTIONS

1. Immediately notify APHIS or CDC and appropriate State and local law enforcement (theft or loss) or appropriate State and local public health agencies (release).
2. The RO must complete Sections 1, 2, and 4 (theft or loss) and Sections 1, 3, and 4 (release). The RO must sign and date the form. If the incident occurred during transit, the RO must complete Section 3 and include a copy of the APHIS/CDC Form 2.
3. The RO faxes or mails the form **within 7 calendar days**.

NOTE: Upon discovery of theft, loss, or release of a select agent or toxin, clinical or diagnostic laboratories and other entities that possess, use or transfer a select agent or toxin contained in a specimen presented for diagnosis, verification, or proficiency testing must report the theft, loss, or release of a select agent or toxin and are required to complete and submit this form (See 42 CFR 73, 7 CFR 331, and 9 CFR 121).

OBTAINING EXTRA COPIES OF THIS FORM

Additional copies of this form are available on APHIS website (http://www.aphis.usda.gov/programs/ag_selectagent/index.html) or CDC website (<http://www.cdc.gov/od/sap>) or by contacting APHIS at (301) 734-5960 or CDC at (404) 498-2255.

WHERE TO SEND THE COMPLETED FORM

Return completed forms to: Agricultural Select Agent Program, 4700 River Road Unit 2, Mailstop 22, Cubicle 1A07, Riverdale, MD 20737 or Centers for Disease Control and Prevention, Select Agent Program, 1600 Clifton Road NE, Mailstop E-79, Atlanta, GA 30333.



REPORT OF THEFT, LOSS, OR RELEASE OF SELECT AGENTS AND TOXINS

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Read all instructions carefully before completing the report. Answer all items completely and type or print in ink. The report must be signed and submitted to: Agricultural Select Agent Program, 4700 River Road Unit 2, Mailstop 22, Cubicle 1A07, Riverdale, MD 20737 or Centers for Disease Control and Prevention, Select Agent Program, 1600 Clifton Road NE, Mailstop E-79, Atlanta, GA 30333.

SECTION 1 – TO BE COMPLETED BY ALL ENTITIES

Entity name		Entity registration number	
Entity address (NOT a post office address)	City	State	Zip Code
Responsible Official (RO) or Facility Director	Telephone	FAX	E-mail
Address (NOT a post office address)	City	State	Zip Code
An internal review of laboratory procedures and policies has been initiated to prevent recurrences of loss of select agents and toxins at this entity: <input type="checkbox"/> Yes <input type="checkbox"/> No			

SECTION 2 – TO BE COMPLETED ONLY FOR REPORTING LOSS OR THEFT OF SELECT AGENTS AND TOXINS

IF LOST ON SITE OR THEFT HAS OCCURRED PROVIDE THE FOLLOWING INFORMATION

Provide a list of all missing select agents and toxins (Complete Section 4)		
Date loss or theft noted	Date of last inventory	Name of principal investigator for laboratory with select agents and toxins
Laboratory building and room	Name and telephone number of local police department notified	
Type of theft (Night break in, armed robbery, etc.)	Symbols or markings on containers (if any)	

Provide a detailed summary of events (attach additional sheets if necessary):

IF LOST OR STOLEN IN TRANSIT PROVIDE THE FOLLOWING INFORMATION

Provide a complete list of missing select agents and toxins (Complete Section 4)	
Attach a copy of the APHIS/CDC Form 2 that was associated with this shipment	
Name of carrier	Airway bill number/tracking number

Provide a detailed summary of events (attach additional sheets if necessary):

Package description (size, shape, description of packaging including number and type of inner packages; attach additional sheets if necessary):

SECTION 2 (CONTINUED) PROVIDE THE FOLLOWING INFORMATION

	SENDER INFORMATION	RECIPIENT INFORMATION
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Name of person				
Name of entity				
CDC/APHIS registration number	CDC	APHIS	CDC	APHIS
PHS/USDA import permit number	PHS	USDA	PHS	USDA
Date shipped				
Telephone				
FAX				
CDC authorization number from transfer form:		APHIS authorization number from transfer form:		
Package with select agents and toxins received by requestor <input type="checkbox"/> Yes <input type="checkbox"/> No		Package with select agents and toxins was tampered with <input type="checkbox"/> Yes <input type="checkbox"/> No		
Other contents of package (e.g., coolant type):				

SECTION 3 – TO BE COMPLETED ONLY FOR RELEASE OF SELECT AGENTS AND TOXINS		
Provide a list of all select agents and toxins released (Complete Section 4)		
Date of release	Time of release	Name of principal investigator for laboratory with select agents and toxins
Location of exposure or release (give laboratory building, room, area and surface or space involved)		
Name and telephone number of local and or state health dept. notified		Name and telephone number of emergency responders
Biosafety level of laboratory where exposure occurred		
Names of person(s) involved in exposure (attach additional sheet if necessary)		Number of animals exposed
Injuries <input type="checkbox"/> No <input type="checkbox"/> Yes (If Yes, give names and occupations of individuals injured)		
Exposures <input type="checkbox"/> No <input type="checkbox"/> Yes (If Yes, give names and occupations of individuals exposed)		
Medical treatment was required <input type="checkbox"/> No <input type="checkbox"/> Yes (If Yes, explain)		
Provide a detailed summary of events (attach additional sheets if necessary; provide sufficient information so that the severity of the release can be understood):		
Provide a summary of actions taken: <input type="checkbox"/> Called ambulance <input type="checkbox"/> Called fire department <input type="checkbox"/> Closed laboratory doors <input type="checkbox"/> Closed building <input type="checkbox"/> Consulted MSDS or chemical database <input type="checkbox"/> Called police department (case #) <input type="checkbox"/> Other (explain):		

Provide a summary of clean up actions taken (attach additional sheets if necessary):							
SECTION 4 – TO BE COMPLETED BY ALL APPLICANTS							
LIST OF SELECT AGENTS AND TOXINS LOST, STOLEN OR RELEASED							
	Select agents and toxins	Characterization of agent	Number of vials	Form (powder/liquid/slant)	Vol or wt per vial (e.g., ml, mg, ng)	Total quantity	Concentration/vial (e.g., 10 ⁸ pfu/ml)
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							

I hereby certify that the information contained on this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of 42 CFR 73, 9 CFR 121, or 7 CFR 331 may result in civil or criminal penalties, including imprisonment.

Signature of Responsible Official (RO): _____ Typed or printed name of RO: _____

Date: _____

Public reporting burden: Public reporting burden of providing this information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-24, Atlanta, Georgia 30333; ATTN: PRA (0920-0576).